URGENT
FIELD SAFETY NOTICE

November 29, 2019

Dear Johnson & Johnson Vision Customer:

RE: Voluntary Recall of Healon GV® PRO OVDs

Johnson & Johnson Surgical Vision, Inc. (JJSV, part of the Johnson & Johnson Vision group of companies) is recalling 21 product lots of Healon GV® PRO (this "**Action**"). **This Action only affects the Healon GV® PRO Ophthalmic Viscosurgical Device (OVD) listed on page 4. No other JJSV Healon® OVD products are affected by this Action.** The Healon GV® PRO OVD lot number is displayed on the end of each individual unit carton (see page 3 for label example). The OVD lot number is also present on each individual syringe packaging tray and each syringe.

JJSV has voluntarily initiated this Action due to complaints that the Healon GV® PRO may be difficult to remove from the eye, leading to increased postoperative Intraocular Pressure (IOP) requiring additional intervention. There have also been reports of potential clogging of phacoemulsification equipment tubing, which may lead to delay in the procedure or ocular injury. **You are receiving this notice because our records indicate that you received Healon GV® PRO impacted by this Action.**

Because you have received impacted product, **please immediately take the following actions**:

1. Compare your inventory against the attached list on page 4.
2. **Discontinue** using and remove from your inventory all affected Healon GV® PRO OVD lots listed on page 4 of this letter. **Note that you can continue to use all other JJSV OVD lots not affected by this recall.**
3. **EVEN IF YOU HAVE NO INVENTORY,** please complete the attached Customer Reply Form (on page 5). JJSV requires this information for reconciliation purposes with regulatory agencies.

If you have inventory of any of the OVDs with the lot number listed on page 4, please complete the Customer Reply Form, noting the lot numbers of the OVDs and contact Customer Support at ***[Insert regional contact number]*** to arrange pick up of affected product to be returned. **Returned product will NOT require refrigerated shipping.** Any returned product will be replaced/substituted.

The completed Customer Reply Form should be faxed to JJSV Quality Assurance at ***[Insert regional fax number]*** or emailed to **[insert regional email address]** within **3 business days of receipt of this letter.**

This notice should be shared with anyone who needs to be aware within your organization or to any organization where the potentially affected products have been transferred.

If you have product complaints or adverse events to report regarding the use of these Healon GV® PRO OVD, please inform JJSV by calling ***[Insert regional contact number]***. If you do report a complaint, please provide the Healon GV® PRO OVD Lot Number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.

National Competent Authorities have been notified of this action.

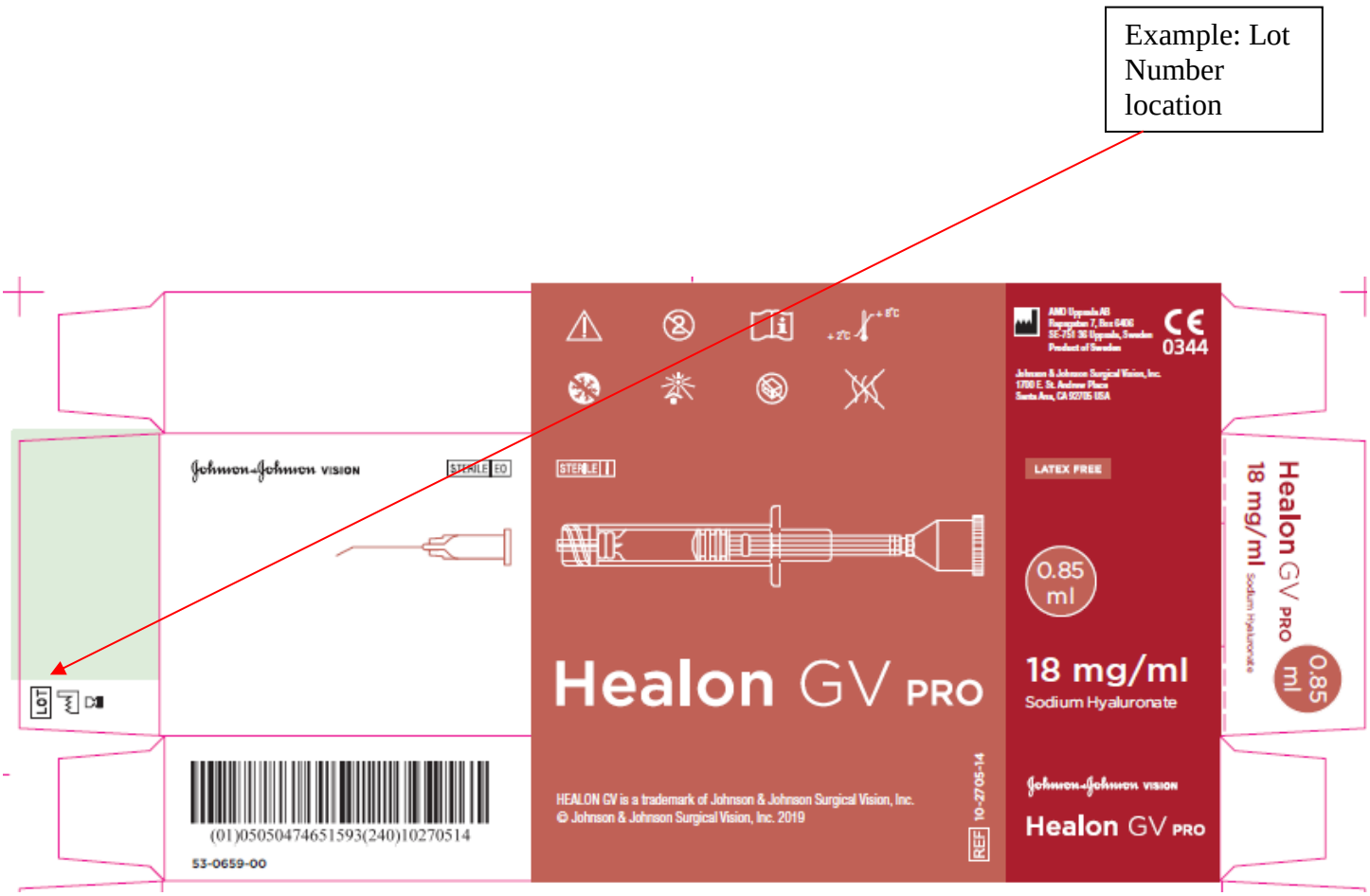
This voluntary action reflects JJSV's commitment to high quality standards and ensuring that our products fully meet your expectations. JJSV remains fully committed to serving you and your patients with safe and effective products. We recognize the inconvenience this causes you and appreciate your assistance in expediting the return of this product.

Sincerely,

_____

Michelle McCabe
Quality Systems Manager
Johnson & Johnson Surgical Vision, Inc.

Product Unit Carton Label Example



EMEA Lot Numbers Affected by Recall

Model	Lot No.
Healon GV® PRO 0.85 mL	UE31098
Healon GV® PRO 0.85 mL	UE31204
Healon GV® PRO 0.85 mL	UE31283
Healon GV® PRO 0.85 mL	UE31306
Healon GV® PRO 0.85 mL	UE31364
Healon GV® PRO 0.85 mL	UE31409
Healon GV® PRO 0.85 mL	UE31467
Healon GV® PRO 0.85 mL	UE31476
Healon GV® PRO 0.85 mL	UE31507
Healon GV® PRO 0.85 mL	UE31519

JJSV Product RECALL Letter Dated November 29, 2019

2019 JJSV HEALON GV® PRO RECALL CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via Fax: [fax number] *or* email: *[Email address]*.

Please place an "X" in one of the boxes below.

- ☐ All affected products have been used or discarded.
- ☐ JJSV Representative has returned all affected product inventory on our behalf.
- ☐ Product(s) was(were) previously returned to JJSV.
- ☐ We are returning affected products. **RGA #** _____

Lot Number	Quantity of Healon GV® PRO to be Returned	Lot Number	Quantity of Healon GV® PRO to be Returned

JJV Account Number:	
Account Name:	
Address:	
City, State, Zip Code	
Country	
Telephone Number:	

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Product Recall letter:

Name: (print) _____

Title/Position: _____

Signature: _____

Date: _____